FEB 14 2012

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Mary Kruitwagen
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United States

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This summary was prepared on January 16, 2012.

2. a) The name of the subject device is Philips SureSigns VS3 Vital Signs Monitor and the SureSigns VS4 Vital Signs Monitor.

b) The trade name of the device is SureSigns VS3 Vital Signs Monitor and the SureSigns VS4 Vital Signs Monitor.

c) The common usual name for both the VS3 and the VS4 are multi-parameter patient monitor

4) The Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1435, II	DXG	Computer, Diagnostic, Preprogrammed, Single-function
	870.2700, II	DQA	Oximeter
	870.2850, I	DSA	Cable, transducer and electrode, patient connector
	870.2810, I	DSF	Recorder, Paper Chart
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The modified devices are substantially equivalent to previously cleared Philips device, SureSigns VS3 cleared under K082280 and K090483.

4. The modifications are as follows:

- Introduction of the VS4 Vital Signs monitor (the predicate device is VS3)
- Modify VS3

5. The subject devices have the same intended use as the legally marketed predicate device SureSigns VS3. The Indications for Use is unchanged although the available measurements are listed.

6. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same algorithms for the measurements as the predicate devices.

   Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject device. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VS3 Vital Signs monitor and the Philips SureSigns VS4 Vital Signs monitor meet all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 14 2012

Philips Medical Systems
c/o Ms. Mary Kruitwagen
3000 Minuteman Road
Andover, MA 01810

Re: K120132
Trade/Device Name: SureSigns VS3/VS4 Vital Signs Monitors
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Codes: DXN, DQA, DSJ, DSK, DXG, DSA, DSF, FLL
Dated: January 16, 2012
Received: January 27, 2012

Dear Ms. Kruitwagen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K120132

Device Name: SureSigns VS3 (reference numbers: 863069, 863070, 863071, 863072, 863073, 863074)
SureSigns VS4 (reference numbers: 863283)

Indications for Use

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Standard and optional parameters include:

- NBP
- SpO_2
- Temperature

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120132